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Attorney Docket No. 00626A/HG

**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Applicants : Takafumi KOHAMA et al.
Serial No. : 09/943,712
Filed : August 31, 2001
For : PHARMACEUTICAL COMPOSITION
Art Unit : 1614
Examiner : Dwayne C. Jones

AMENDMENT UNDER 37 CFR 1.111

COMMISSIONER FOR PATENTS
Washington, D.C. 20231

S I R :

This is in response to the Office Action dated
March 26, 2002, the term for which having been extended three
months by the enclosed PETITION and fee to expire
September 26, 2002.

Claims 1-28 are pending in the application. All of the
claims have been rejected as unpatentable over a combination of
Bocan WO 97/16184 and Kamiya et al. EP 866,059.

Bocan is cited for teaching a combination of ACAT inhibitors
and HMG-CoA-reductase inhibitors. Kamiya is cited for teaching
various ACAT inhibitors and their utility (including the ACAT
inhibitor which is required in the pharmaceutical composition of
the present claims to be used in combination with an HMG-CoA
reductase inhibitor.

CERTIFICATE OF MAILING

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date noted below.

Attorney: Marshall J. Chick

Dated: September 24, 2002

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10-4-02

The present invention is a combination of a very specific ACAT inhibitor (or a pharmaceutically acceptable salt thereof) with an HMG-CoA reductase inhibitor. Specific particularly favorable reductase inhibitors are defined in claims 2-7, the corresponding claims 9-14 and various corresponding method claims of the same or similar scope. As pointed out in the Brief Summary of the Invention (page 3 of the specification), the specific ACAT inhibitor of the present invention when used in combination with an HMG-CoA reductase inhibitor has been found to provide useful prophylactic or therapeutic properties.

The test data summarized in Table 1 on page 14 and Table 2 on page 17 of the specification shows an unexpectedly superior effect when the combination is used as compared with each component separately. In some cases one component alone does not appear to have any effect or a reverse effect (see TC and HTL results for pravastatin in Table 1 as compared with the claimed combination results). Also, in Table 2, the pravastatin appears to have a reverse effect (that is higher than the control) although when combined with the other active agent the results are extremely good and could not have been expected.

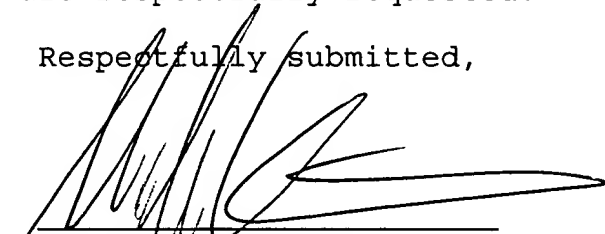
In view of the above, it is requested that the *prima facie* obviousness position taken by the Examiner be re-considered. There is evidence in the specification that the present invention

combination provides results which could not have been expected from the individual components.

In view of the above, reconsideration of the rejection and allowance of the application are respectfully requested.

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Respectfully submitted,


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